

(10)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 862 925 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention

of the grant of the patent:

01.09.2004 Bulletin 2004/36

(51) Int Cl.: A61N 1/05

(21) Application number: 98301389.7

(22) Date of filing: 25.02.1998

(54) Sacral medical electrical lead

Sakrale medizinische elektrische Zuleitung

Electrode médicale sacrée

(84) Designated Contracting States:

CN FR GB IT LI NL SE

(30) Priority: 03.03.1997 US 811054

(43) Date of publication of application:

09.09.1998 Bulletin 1998/37

(73) Proprietor: Medtronic, Inc.

Minneapolis, Minnesota 55432-5604 (US)

(72) Inventors:

- Moumans, Farid
59132 Trelon (FR)
- Robinet, Jean
59186 Anor (FR)

• Deruyver, Benoît

59440 Avesnes-Sur-Helpe (FR)

• Mazza, Ronald Lee

Burnsville, Minnesota 55337 (US)

(74) Representative: Hughes, Andrea Michelle

Frank B. Dehn & Co.,

European Patent Attorneys,

179 Queen Victoria Street

London EC4V 4EL (GB)

(56) References cited:

WO-A-95/19504

US-A- 4 869 351

US-A- 4 639 669

US-A- 5 423 677

US-A- 5 505 201

US-A- 5 531 778

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] This invention relates to an anchoring system and specifically to a sacral medical electrical lead which may be implanted and reliably fixed for a temporary period of time within the sacrum in a minimally invasive manner.

[0002] The present invention relates to the art of selective nerve stimulation. The invention finds particular application in conjunction with urination control and will be described with particular reference thereto. It is to be appreciated that the invention is also applicable to control other aspects of the nervous system, such as for fecal incontinence, penile erection, and others.

[0003] The organs involved in bladder, bowel, and sexual function receive much of their control via the second, third, and fourth sacral nerves, commonly referred to as S2, S3 and S4 respectively. Electrical stimulation of these various nerves has been found to offer some control over these functions. Several techniques of electrical stimulation may be used, including stimulation of nerve bundles within the sacrum.

[0004] The sacrum, generally speaking, is a large, triangular bone situated at the lower part of the vertebral column, and at the upper and back part of the pelvic cavity. The spinal canal runs throughout the greater part of this bone. It lodges the sacral nerves, and is perforated by the anterior and posterior sacral foramina through which these pass out.

[0005] Several systems of stimulating sacral nerves exist. For example, U.S. Patent No. 4,507,635 to Taniguchi et al. entitled "Method and System for Controlling Bladder Evacuation", and the related U. S. Patent No. 4,739,764 to Luo et al. entitled "Method for Stimulating Pelvic Floor Muscles for Regulating Pelvic Viscera", disclose implanting an electrode on at least one nerve controlling the bladder. In one embodiment the electrode is percutaneously implanted through the sacrum and the sacral foramen of the sacral segment S3 for purposes of selectively stimulating the S3 sacral nerve. The electrode is positioned using a hollow spinal needle through a foramen (a singular foramina) in the sacrum. The electrode is secured by suturing the lead body in place. U. S. Patent No. 4,589,351 to Tung entitled "Apparatus and Method for Stimulating Micturition and Certain Muscles in Paraplegic Mammals", discloses use of electrodes positioned within the sacrum to control bladder function.

[0006] US-A-4,533,859 also discloses a spinal nerve electrode.

[0007] Typically electrical stimulation of the nerves within the sacrum is accomplished by positioning a lead having at least one electrode at its distal end through a foramen of the sacrum and proximate the nerve. Not all patients, however, are suitable for such stimulation. In fact, at present there is not a reliable screening tool to identify patients who would or would not benefit from sacral nerve stimulation other than to actually stimulate such nerves.

[0008] Placing a lead into the sacrum in order to assess the efficacy of sacral nerve stimulation may be performed percutaneously, that is, simply using a needle. Leads implanted in such a manner, however, have to date been difficult to reliably anchor in position. Techniques such as taping the exterior lead body to the patient are not wholly satisfactory. Other techniques which are effective to anchor a sacral lead, such as screwing the lead to the sacral bone, are much too invasive for a screening procedure. Thus there exists a need for a medical electrical lead which may be safely and effectively implanted into the sacrum and anchored within in a minimally invasive manner.

[0009] The present invention aims to provide a sacral medical electrical lead which may be implanted and reliably fixed for a temporary period of time within the sacrum in a minimally invasive manner.

[0010] According to the invention, there is provided a medical electrical lead comprising:

a lead body, the lead body having an electrical conductor positioned within an insulator sheath; means for electrically coupling the electrical conductor to a pulse generator; the means for electrical coupling located on a proximal end of the lead body; and an electrode located on a distal end of the lead body, the electrode electrically coupled to the conductor; characterized by means for anchoring the electrode within the sacrum, the anchoring means being remote from the electrode; and wherein the outer diameter of the anchoring means is no greater than the lead body outer diameter.

[0011] In the preferred embodiment the anchoring means comprises a notched section in which the insulation of the lead body presents a macroscopically roughened surface which can thereby engage into tissue without causing damage to the tissue.

[0012] Preferred embodiments of the invention will now be described by way of example only, with reference to the accompanying drawings.

FIG. 1 is a posterior view of the spine showing the location of the sacrum relative to an outline of a body.

FIG. 2A is a side view of the sacrum having a lead implanted.

FIG. 2B is a sectional view of the sacrum showing a stimulation system which features a medical electrical lead of the present invention placed within the sacrum.

FIG. 3 is a side view of a medical electrical lead of the present invention.

FIG. 4 is a sectional view of the lead of FIG. 3 across a ridge.

FIG. 5 is a sectional view of the lead of FIG. 3 across

a furrow.

FIG. 6 is a sectional view of the lead of FIG. 3 across a portion of lead body proximal to the anchoring portion.

FIG. 7 is a view of an alternative lead.

FIG. 8 is a view of an alternative lead.

[0013] The FIGS. are not necessarily to scale.

[0014] FIG. 1 is a posterior view of the spinal column 1 showing the location of the sacrum 2 relative to an outline of a body 3. As seen, the sacrum 2 has a series of holes, known as foramina 4, therethrough. Each foramen 4 (as they are referred to in the singular) provides access to the sacral ventral nerves (not shown). As discussed above, electrical stimulation of these nerves is useful to effect control of an organ, such as a bladder (not shown).

[0015] FIG. 2A is a side view of the sacrum having a lead implanted. As seen, the sacrum 2 has a series of foramina 4 located near the dorsal surface 5 of a patient 3. Lead 100 may be inserted using a percutaneous procedure into the foramina so that the electrode at the distal end is positioned near the sacral nerve.

[0016] FIG. 2B is the side sectional view of a lead 100 implanted into the sacrum. As seen, the lead has an electrode 103 at its distal end. Positioned remote from the electrode along the lead body is anchoring portion 104. Through this configuration the electrode may be positioned adjacent the sacral nerve while the anchoring portion is remote from the sacral nerve. This permits the electrode to be reliably anchored next to the nerve without causing damage to the nerves.

[0017] For example, electrode 103 could be percutaneously placed on the S5 sacral nerve with the external extremity of the wire attached to the electrode then being taped to the skin, along with a receiver connected thereto. The patient could then resume his day-to-day lifestyle and be allowed to stimulate the nerve or nerves artificially via the receiver (not shown). If the response is positive and complete relief is achieved, the electrode or electrodes could be permanently implanted or temporarily implanted for the purpose of correcting any dysfunction by "retraining" the nerve and associated muscles. Should little or no improvement result, the same procedure could be followed to accurately ascertain which nerve or nerves require stimulation. Thus, this invention provides electrodes not only for the implantation in the sacral nervous system for controlling evacuation of a visceral organ or the like, but also electrodes to rehabilitate muscle dysfunction by neuromodulation of muscular behavior.

[0018] FIG. 3 is a side view of a medical electrical lead of the present invention. As seen lead 100 has essentially three sections, connector pin 101, lead body 102, and electrode 103. Connector pin 101 is preferably a stainless steel platinum iridium alloy. Likewise, electrode 103 is preferably a stainless steel platinum iridium alloy. Lead body 102 is preferably constructed with a

bundle stranded conductor of stainless steel covered by a sheath of PTFE. Of course other materials may also be selected for either the conductor or sheath. As seen, located at the distal end of lead body is anchoring portion 104. Anchoring portion 104 preferably comprises a macroscopically roughened surface which can thereby engage into the sacral tissue without causing damage to the sacral tissue. In the preferred embodiment the anchoring portion consists of a series of smaller diameter sections, called notches 110 positioned in between a series of larger diameter sections called ridges 111. As discussed above these sections permit the anchoring portion of the lead body to engage within the tissue above the sacrum so as to permit the lead to be reliably positioned without invasive procedure or damaging tissue. In particular, the ridges are able to engage in a non destructive manner with the tissue so as to permit the electrode to be reliably anchored within the sacrum near a nerve.

[0019] In the preferred embodiment this lead body has a total length 458 +/- 6 mm. The electrode is preferably 6 mm in length. Anchoring portion 104 is between 20 and 40 mm long with 30 mm preferred. The electrode preferably has a diameter of 0.6 mm as compared to the lead body which preferably has a diameter of 0.7 mm. The notches preferably have a diameter of 0.8 mm, each notch and ridge are preferably 1.5 mm in length. The lead body is most flexible along the anchoring portion.

[0020] FIG. 4 is a sectional view of the lead of FIG. 3 across a ridge 111. As seen, the ridge is formed by covering conductor 119 with a layer of inner insulation 120 and with a layer of outer insulation 121. The inner insulation is preferably PTFE and outer insulation is preferably polyurethane. Outer insulation is preferably at least 0.0051 mm (0.0002 inches) in thickness. As seen the ridge has an outer diameter D-4.

[0021] FIG. 5 is a sectional view of the lead of FIG. 3 across a notch. As seen a furrow is formed by the absence of the inner insulation 120 but still with the presence of the outer insulation 121. In the preferred embodiment the ridges and notches are manufactured through first covering the conductor with the inner insulation and then removing portions of the inner insulation in the area of the anchoring portion all the way down until the conductor is exposed. Next the anchoring portion is covered with a coating of the outer insulation such that the formerly exposed portions of the conductor are covered and the entire length of the lead body is electrically insulated.

[0022] FIG. 6 is a sectional view of the lead of FIG. 3 across a portion of the lead body proximal to the anchoring portion. As seen insulation 120 covers conductor 119. The lead body has an outer diameter D-5. As seen in a comparison with FIG. 4, outer diameter D-5 is substantially the same as the outer diameter of the ridge, D-4. In the preferred embodiment the lead body outer diameter is no greater than 0.535 mm (0.021 inches) anywhere along its length, including along anchoring

portion.

[0023] Of course, other schemes may also be used to anchor the lead within the sacral tissue and still be within the scope of the present invention. Such schemes include providing lead body insulation as well as geometries which have a higher friction as compared to conventional smooth outer surface lead bodies. An example of an alternative may be seen in FIG. 7. As seen, lead 200 features an electrode 103 at its distal end coupled to conductor 119 as already discussed above. Anchoring portion 104 is constructed through a second piece 611 of insulative material wrapped about the exterior of the lead body insulative sheath. Through this construction a macroscopically roughened area along lead body remote from the electrode is created. As discussed above this permits the lead body to engage into tissue and thus anchor electrode near a nerve without damaging tissue or the nerve.

[0024] A further alternative embodiment is seen in FIG. 8. As seen lead 700 features an electrode 103 at its distal end coupled to conductor 119 as already discussed above. Anchoring portion 104 is constructed through a series of indentations 710 pressed along the exterior of the lead body insulative sheath which form ridges 711. In the preferred embodiment the ridges have the same outer diameter as does the smooth portion 713 of lead body. Through this construction a macroscopically roughened area along lead body remote from the electrode is created. As discussed above this permits the lead body to engage into tissue and thus anchor electrode near a nerve without damaging tissue or the nerve.

[0025] Although the invention has been described in detail with particular reference to a preferred embodiment and alternative embodiments thereof, it will be understood variations and modifications can be effected within the scope of the following claims.

Claims

1. A medical electrical lead comprising:

a lead body (102), the lead body having an electrical conductor (119) positioned within an insulator sheath (120);
means (101) for electrically coupling the electrical conductor to a pulse generator, the means for electrical coupling located on a proximal end of the lead body; and
an electrode (103) located on a distal end of the lead body, the electrode electrically coupled to the conductor (119);
means (104, 611) for anchoring the electrode (103) within the sacrum; and wherein the outer diameter of the anchoring means is no greater than the lead body outer diameter, **characterized by the anchoring means (104) being remote from the electrode (103).**

2. A medical electrical lead according to claim 1 wherein the anchoring (104) means are located at a distance between 1.5 mm and 30.5 mm from the electrode, the anchoring means having a length of at least 29.5 mm.
3. A medical electrical lead according to claim 1 wherein the means for anchoring (104) comprising a series of notches (110) within the lead body.
4. A medical electrical lead according to claim 2 or any claim dependent thereon wherein the insulator sheath comprises a first, outer insulator sheath (121) and a second, inner insulator sheath (120).
5. A medical electrical lead according to claim 4 wherein the means for anchoring the electrode (103) within the sacrum comprises a series of notches within the first insulator sheath, the notches extending through the thickness of the first insulator sheath such that the electrical conductor is not covered by the first insulator sheath in the area of the notch; said second insulator sheath (121) fixed to the electrical conductor not covered by the first insulator sheath in the area of a notch.
6. A medical electrical lead according to claim 5 wherein the second insulator sheath is polyurethane.
7. A medical electrical stimulation system comprising:
a medical electrical stimulator; and
a medical electrical lead as claimed in any of claims 1 to 6 coupled to the stimulator.

Patentansprüche

1. Elektrische Zuleitung für medizinische Zwecke, welche folgendes umfasst:
- einen Zuleitungskörper (102), welcher einen Stromleiter (119) aufweist, der im Inneren einer Isolierumhüllung (120) positioniert ist;
- eine Einrichtung (101) zur elektrischen Ankopplung des Stromleiters an einen Impuls-generator, wobei die Einrichtung zur elektrischen Ankopplung auf einem proximalen Ende des Zuleitungskörpers liegt; und
- eine Elektrode (103), die sich auf einem distalen Ende des Zuleitungskörpers befindet, wobei die Elektrode elektrisch mit dem Stromleiter (119) gekoppelt ist;
- eine Einrichtung (104, 611) zum Verankern der Elektrode (103) innerhalb des Kreuzbeins, wobei der Außendurchmesser der Verankerungseinrichtung nicht größer als der Außendurchmesser des Zuleitungskörpers ist;

dadurch gekennzeichnet, dass die Verankerungseinrichtung (104) von der Elektrode (103) entfernt liegt.

2. Elektrische Zuleitung für medizinische Zwecke gemäß Anspruch 1, bei welcher die Verankerungseinrichtungen (104) in einem Abstand von 1,5 mm bis 30,5 mm von der Elektrode angeordnet sind, wobei die Verankerungseinrichtung eine Länge von mindestens 29,5 mm aufweist.

3. Elektrische Zuleitung für medizinische Zwecke gemäß Anspruch 1, bei welcher die Verankerungseinrichtung (104) aus einer Reihe von Einkerbungen (110) in dem Zuleitungskörper besteht.

4. Elektrische Zuleitung für medizinische Zwecke gemäß Anspruch 2 oder jedem seiner Unteransprüche, bei welcher die Isolierumhüllung aus einer ersten außen liegenden Isolierumhüllung (121) und einer zweiten, innen liegenden Isolierumhüllung (120) besteht.

5. Elektrische Zuleitung für medizinische Zwecke gemäß Anspruch 4, bei welcher die Einkerbung zum Verankern der Elektrode (103) innerhalb des Kreuzbeins aus einer Reihe von Einkerbungen in der ersten Isolierumhüllung besteht, wobei sich die Einkerbungen durch die gesamte Dicke der ersten Isolierumhüllung in der Weise erstrecken, dass der Stromleiter in dem Bereich der Einkerbung von der ersten Isolierumhüllung nicht abgedeckt ist; wobei die zweite Isolierumhüllung (121), die am Stromleiter befestigt ist, in dem Bereich einer Einkerbung von der ersten Isolierumhüllung nicht abgedeckt ist.

6. Elektrische Zuleitung für medizinische Zwecke gemäß Anspruch 5, bei welcher die zweite Isolierumhüllung aus Parylen besteht.

7. System zur elektrischen Stimulierung für medizinische Zwecke, welches folgendes umfasst:

einen elektrischen Stimulator für medizinische Zwecke; und
eine elektrische Zuleitung für medizinische Zwecke nach einem der Ansprüche 1 bis 6, welche an den Stimulator gekoppelt ist.

Revendications

1. Fil d'aménée électrique médical, comprenant :
un corps de fil (102), ledit corps de fil ayant un conducteur électrique (119) positionné dans une gaine isolante (120);
des moyens (101) pour coupler électriquement

le conducteur électrique à un générateur d'impulsions, lesdits moyens de couplage électrique étant situés sur une extrémité proximale du corps de fil; et
une électrode (103) située sur une extrémité distale du corps de fil, ladite électrode étant électriquement couplée au conducteur (119);
des moyens (104, 611) pour ancrer l'électrode (103) à l'intérieur du sacrum; et dans laquelle le diamètre extérieur des moyens d'ancrage n'est pas supérieur au diamètre extérieur du corps de fil;

caractérisé en ce que les moyens d'ancrage (104) sont éloignés de l'électrode (103).

2. Fil d'aménée électrique médical selon la revendication 1, dans lequel les moyens d'ancrage (104) sont situés à une distance entre 1,5 et 30,5 mm de l'électrode, les moyens d'ancrage ayant une longueur d'au moins 29,5 mm.

3. Fil d'aménée électrique médical selon la revendication 1, dans lequel les moyens d'ancrage (104) comprennent une série d'encoches (110) dans le corps de fil.

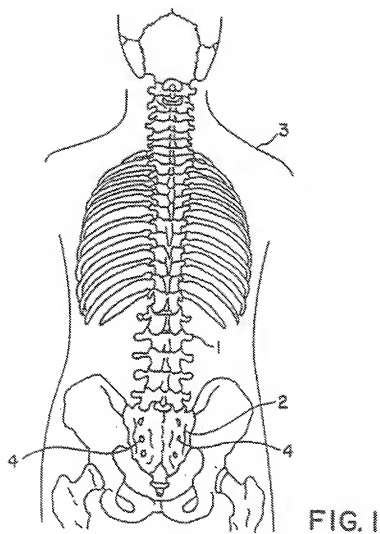
4. Fil d'aménée électrique médical selon la revendication 2 ou une quelconque revendication dépendante de celle-ci, dans lequel la gaine isolante comprend une première gaine isolante extérieure (121) et une seconde gaine isolante intérieure (120).

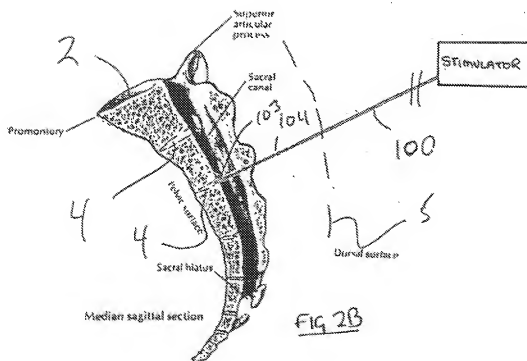
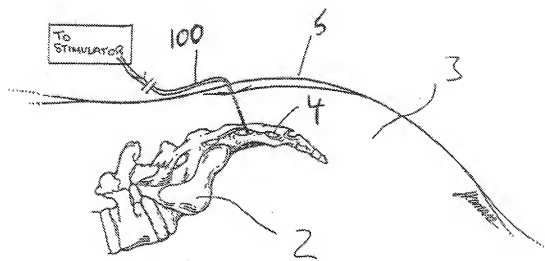
5. Fil d'aménée électrique médical selon la revendication 4, dans lequel les moyens pour ancrer l'électrode (103) dans le sacrum comprennent une série d'encoches dans la première gaine isolante, les encoches s'étendant à travers l'épaisseur de la première gaine isolante de telle façon que le conducteur électrique n'est pas recouvert par la première gaine isolante dans la zone de l'encoche; ladite seconde gaine isolante (121) étant fixée sur le conducteur électrique qui n'est pas couvert par la première gaine isolante dans la zone d'une encoche.

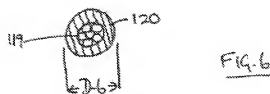
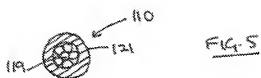
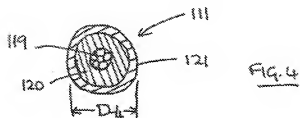
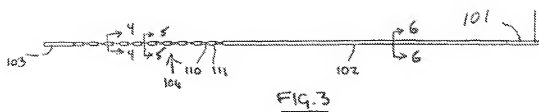
6. Fil d'aménée électrique médical selon la revendication 5, dans lequel la seconde gaine isolante est en parylène.

7. Système de stimulation électrique médical comprenant :

un stimulateur électrique médical; et
un fil d'aménée électrique médical tel que revendiqué dans l'une quelconque des revendications 1 à 6, couplé au stimulateur.







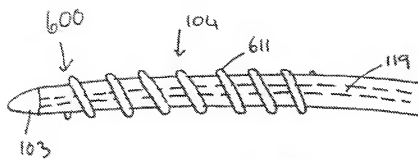


FIG. 7

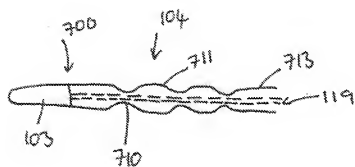


FIG. 8